UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, IPR PHARMACEUTICALS, INC., and SHIONOGI SEIYAKU KABUSHIKI KAISHA,	
Plaintiffs,	Civil Action No. 07-809-JJF-LPS
v.	**REDACTED VERSION DI 28**
APOTEX, INC., and APOTEX CORP.,	
Defendants.	

PLAINTIFFS' OPPOSITION TO APOTEX CORP.'S MOTION TO DISMISS

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Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, IPR Pharmaceuticals, Inc., and Shionogi Seiyaku Kabushiki Kaisha (collectively "AstraZeneca") oppose the motion of Apotex Corp. to dismiss portions of the complaint for reasons set forth more fully below.

I. THE NATURE AND STAGE OF THE PROCEEDING

This is an action for infringement of U.S. Reissue Patent RE37,314 ("the '314 patent") under 35 U.S.C. § 271(e)(2)(A) and for a declaratory judgment under 35 U.S.C. § 271(a) based on threatened future infringement. The action results from the filing by Apotex Inc. ("Apotex Canada") and Apotex Corp. ("Apotex USA") (collectively "Apotex") of Abbreviated New Drug Application (ANDA) No. 79-145 to market generic versions of AstraZeneca's highly successful drug CRESTOR®, before the '314 patent expires.

Apotex is one of seven generic pharmaceutical companies to challenge '314 patent by requesting FDA approval to sell generic CRESTOR® before the patent's expiration date. Seeking to resolve the multiple challenges to its patent rights, AstraZeneca filed seven related patent infringement actions in the District of Delaware on December 11, 2007 (C.A. Nos. 07-805, 07-806, 07-807, 07-808, 07-809, 07-810, and 07-811). AstraZeneca's action against Apotex in Delaware is Civil Action No. 07-809.

In addition to Apotex USA's challenge to the Court's subject matter jurisdiction, Apotex Canada challenged the Court's personal jurisdiction, seeking dismissal or transfer to the Middle District of Florida, where Apotex filed a declaratory judgment action against AstraZeneca, regarding a different patent.

II. SUMMARY OF ARGUMENT

1. As the wholly-owned subsidiary and U.S. marketing arm of Apotex Canada, Apotex USA signed and certified as to the accuracy of the ANDA and transmitted the

application to the FDA. Courts facing analogous circumstances, where the U.S. subsidiary and marketing arm of a foreign parent has signed and certified the ANDA, have held that the U.S. subsidiary participated in the submission of the ANDA and may be sued under 35 U.S.C. § 271(e)(2)(A).

2. Declaratory judgment jurisdiction is proper over Apotex's anticipated acts of infringement under 35 U.S.C. § 271(a), because the parties' controversy is sufficiently immediate and real to present an actual controversy, and the Court should exercise its discretion to hear the matter for reasons of policy and judicial economy.

3. Apotex Canada is not an indispensable party to this action, because (a) Apotex Canada and Apotex USA share identical economic interests in defending the lawsuit, (b) Apotex Canada has demonstrated its willingness to litigate in Delaware in several past actions and can participate in this action, and (c) the remedies sought by AstraZeneca, enjoining the FDA's approval of the ANDA until after the '314 patent expires and enjoining the U.S. sale of generic rosuvastatin calcium, would be essentially the same if Apotex Canada was not a party.

III. STATEMENT OF FACTS

This case relates to AstraZeneca's CRESTOR® rosuvastatin calcium product, and Apotex's efforts to sell a generic version of CRESTOR® before the patent on the active ingredient, rosuvastatin calcium, expires. The discovery of rosuvastatin calcium resulted in one of the most potent cholesterol-lowering drugs now available. Over 11 million patients in the United States have been prescribed CRESTOR®, and over 110 million prescriptions have been written worldwide for CRESTOR®. (D.I. 1 at ¶ 9.)

Apotex's ANDA relies on the years of clinical testing conducted by AstraZeneca to demonstrate the safety and efficacy of its proposed generic version of CRESTOR®, without the need to duplicate that testing. *See, e.g.*, 21 C.F.R. §§ 314.94 and 320.21. If the application is

approved, Apotex Canada will manufacture the generic product, and Apotex USA, a Delaware corporation and wholly-owned subsidiary of Apotex Canada, will sell the product in the United States.

Apotex USA signed and certified the ANDA's accuracy and completeness for submission to the FDA. In doing so, Apotex USA (1) verified that the information in the application had been reviewed and was accurate, (2) agreed to update the application with any new safety information, and (3) agreed to comply with various regulations following ANDA approval.

IV. ARGUMENT

A. Count I Should Be Maintained Against Apotex USA

Apotex USA contends that 35 U.S.C. § 271(e)(2) creates a single act of patent infringement that is performed solely by the person who "submits an ANDA to the FDA for approval as an applicant." (D.I. 14 at 4.) Apotex is wrong, because the tort of patent infringement under § 271(e)(2) is not limited to a single entity, and the regulatory definition of "applicant" is not limited to the owner of the ANDA.

1. Hatch-Waxman Liability Is Not Limited to an FDA "Applicant"

Under the Hatch-Waxman Act,

> [i]t shall be an act of infringement to submit . . . an [ANDA application to the FDA] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). The statute, by its terms, does not limit liability for "submit[ting]" an ANDA to a single entity, nor does the statute limit liability to the ANDA "applicant." Instead, liability under the statute extends to those who submit an ANDA for FDA approval with the purpose "to engage in the commercial manufacture . . . or sale of a drug." Both of the Apotex

entities participated in the submission of the ANDA with the purpose of commercially manufacturing (Apotex Canada) and selling (Apotex USA) generic rosuvastatin calcium.

Moreover, the regulatory definition of an "applicant" confirms that there can be multiple "applicants" in addition to the ANDA owner.[1] An applicant includes anyone who owns, submits, amends, or supplements the application. Consequently, Apotex USA, as one who submitted the ANDA and certified that it will update the application as necessary, is also an "applicant" and one who submitted the ANDA for approval to engage in commercial manufacture or sale of generic rosuvastatin calcium. Thus, whether Apotex USA is viewed as the agent of Apotex Canada for purposes of securing regulatory approval, or Apotex Canada is viewed as the agent of Apotex USA for purposes of securing permission to sell in the U.S., both are submitters of the ANDA.

2. Both a Parent and Its Subsidiary Can Infringe Under § 271(e)(2) When They File an ANDA Together

Apotex failed to cite prior precedent, permitting § 271(e)(2) actions against both parent and subsidiary in analogous circumstances. For example, in *Aventis Pharma Deutschland GMBH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 494 (E.D. Va. 2005), the court permitted § 271(e)(2) claims against a foreign parent and its U.S. subsidiary where the subsidiary countersigned the ANDA and "appear[ed] to be the parent's marketing arm in the United States." *See also Wyeth v. Lupin Ltd.*, 505 F. Supp. 2d 303, 306-07 (D. Md. 2007) ("But when a wholly-owned U.S. subsidiary of a foreign corporation exists to distribute foreign-produced generic drugs in the U.S.

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[1] "Applicant" is defined in 21 C.F.R. § 313.3: "Applicant means any person who submits an application or abbreviated application or an amendment or supplement to them under this part to obtain FDA approval of a new drug or an antibiotic drug and any person who owns an approved application or abbreviated application." (Emphasis added.)

and is actively involved in the ANDA process, the subsidiary also 'submits' an ANDA application.").

The U.S. subsidiaries in *Wyeth* and *Aventis* performed a much different role than the unrelated third parties addressed in the two cases on which Apotex relies as contrary authority. *See Smithkline Beecham Corp. v. Geneva Pharms., Inc.*, 287 F. Supp. 2d 576 (E.D. Pa. 2002) and *Smithkline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00-C-2855, 2001 WL 184804 (N.D. Ill. Feb. 20, 2001). In those cases, the patent owner sued unrelated third-party suppliers of the active ingredient used in the drug products, alleging that they had aided the ANDA submissions by providing information about the manufacturing process for the active ingredient. In *Geneva*, for example, the court ruled that the suppliers' conduct was not within the scope of § 271(e)(2) because an act of infringement under that section "is the submission of the ANDA for the purpose of obtaining FDA approval to commercially make . . . or sell a drug claimed in a patent . . . ." *Geneva*, 287 F. Supp. 2d at 584. Unlike Apotex USA, here, the supplier in that case had not submitted an application to make or sell a drug, it had merely submitted information about how the active ingredient was manufactured for the proposed drug.

In fact, *Wyeth* distinguished the *Geneva* and *Pentech* cases, noting that the third-party suppliers were not "involved with filing [the foreign parent's] ANDAs with the FDA, and marketing and distributing the approved generic drugs in the United States." 505 F. Supp. 2d at 306; s*ee also Aventis v. Lupin*, 403 F. Supp. 2d at 492-494. Thus, the *Wyeth* and *Aventis* decisions, instead of the *SmithKline* decisions, are the more applicable precedent and compel the outcome here, *i.e.*, that Apotex USA is subject to suit under § 271(e)(2).

Nevertheless, Apotex USA insists that its only role in the ANDA submission was to act as Apotex Canada's designated agent "for purposes of accepting service of process." (D.I. 14 at

3.) That precise argument was rejected by the court in *Wyeth*, where the U.S. subsidiary's only alleged role was to countersign the ANDA for the alleged "limited purposes of serving process and transmitting [the foreign parent's] ANDA to the FDA." *Wyeth*, 505 F. Supp. 2d at 305-06. The court nevertheless concluded that a subsidiary with that level of active involvement in the ANDA process that "exists to distribute foreign-produced generic drugs in the U.S." for a foreign parent "also 'submits' an ANDA application." *Id.* at 306-07.

Indeed, Apotex USA's countersignature on the ANDA manifests a significant role in the submission of the application.

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Like the parent-subsidiary relationships in the *Wyeth* and *Aventis* decisions, Apotex USA is the U.S. marketing and sales arm of Apotex Canada, both entities intend to benefit from the ANDA. Forming two parts of the whole, each entity is involved in effecting Apotex's U.S. business strategy and carrying out the purpose of the ANDA—to sell generic rosuvastatin calcium in the United States. Thus, Apotex USA has much more at stake here and a broader role in the ANDA submission than one who merely countersigns an ANDA, and that is why following *Aventis* and *Wyeth* to retain Apotex USA in this litigation is the correct approach.

B. Count II Should Not Be Dismissed

1. Recent Controlling Authority Confirms Declaratory Judgment Jurisdiction

The "actual controversy" needed to sustain declaratory judgment jurisdiction arises from Article III of the Constitution, and requires that "the facts alleged, under all the circumstances,

show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 771 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). In *MedImmune*, the Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test for declaratory relief, finding that the test contradicts or conflicts with four prior Supreme Court decisions. *Id.* at 774 n.11; *recognized by SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007) and *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007). Post-*MedImmune*, the Federal Circuit has acknowledged that the boundaries of declaratory judgment jurisdiction are expanded, stating "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise . . . ." *SanDisk*, 480 F.3d at 1381.

Under the expanded standards of *MedImmune*, there is a justiciable controversy over Count II: Apotex has notified both the FDA and AstraZeneca that it intends to sell generic rosuvastatin calcium without license before the '314 patent expires, and AstraZeneca has asserted its patent rights to prevent that activity.

2. Activities that Might Be Protected from Infringement Under the § 271(e)(1) Safe-Harbor Provision Are Relevant to the Inquiry

Apotex argues that "any past, present, and future activity performed by Defendants in connection with the development and submission of information to the FDA, including the preparation and filing of the ANDA application," is protected from liability for patent infringement under 35 U.S.C. § 271(e)(1). (D.I. 14 at 6.) In *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997), the Federal Circuit expressly addressed that issue, ruling

that courts may exercise declaratory judgment jurisdiction even where the case or controversy is "premised in part on actions protected under § 271(e)(1)." *See also Amgen, Inc. v. Hoffman-LaRoche Ltd.*, 456 F. Supp. 2d 267, 276 (D. Mass. 2006) (safe harbor activities may establish an actual controversy). Significantly, the day before this brief was due, the Federal Circuit reaffirmed its decision in the *Glaxo* case, that conduct otherwise protected by the safe harbor may support the Court's exercise of declaratory judgment jurisdiction. *See Amgen, Inc. v. ITC*, No. 2007-1014, slip op. at 14 (Fed. Cir. March 19, 2008) (analyzing the jurisdiction of the International Trade Commission).[2]

Here, Apotex misapplies the § 271(e)(1) safe harbor, because "the protected status of [defendant's] activities leading to its submissions to the FDA does not by itself prevent the district court from considering [plaintiff's] request for declaratory relief because such relief is directed to the time after the ANDA is approved, when § 271(e)(1) no longer provides a shelter against infringement liability." *Glaxo,* 110 F.3d at 1571. Though immune from liability, Apotex's preparations to sell generic rosuvastatin calcium demonstrate, as in *Glaxo*, an actual, justiciable controversy based on threatened future infringement when the safe harbor will no longer apply.

a) Apotex Will Enter the Market as Soon as Legally Possible

The immediacy of the threatened infringement is confirmed by the substantial preparations involved in preparing and filing an ANDA[3] and the significant market value of

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[2] Although the underlying infringement allegations in *Glaxo* and *Amgen v. ITC* were based on § 271(g) (importing a product made overseas by a patented process), the analysis applies with equal force to § 271(a) infringement, because the § 271(e)(1) safe harbor applies to conduct within the scope of both statutes.

[3] An ANDA requires, *at least*: (1) a product formulated for human consumption; (2) completion of manufacturing control testing; (3) human bioequivalency clinical trials; and (4) a

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generic rosuvastatin calcium. Given these efforts and the money at stake, Apotex is unlikely to abandon its plan to sell generic CRESTOR® before the '314 patent expires. In similar circumstances, the court in *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 (N.D. Ill. 2001) found:

> [T]he enormous amount of money at stake [] leads to the inescapable conclusion that defendant plans to enter the market as soon as possible . . . . To hold [there is no declaratory judgment jurisdiction], as defendant requests, would be to close one's eyes to the economic realities of the situation. [The product-at-issue's] sales last year alone amounted to $610,000,000 worldwide.

Id. at 1009 (citations omitted.) *See also Abbott Labs. v. Baxter Healthcare Corp.*, No. 04-C-836, 2004 WL 1878291, at *6 (N.D. Ill. Aug. 16, 2004) ("[T]ime and cost involved in filing an ANDA indicate an intent to market [the generic product at issue]").

b) FDA Approval Is Not Required for Jurisdiction

Apotex argues that there is no immediate controversy, because FDA's approval of the ANDA has not occurred and is not imminent. (D.I. 14 at 7.) FDA approval, however, is not a prerequisite to declaratory judgment jurisdiction. The filing of an ANDA itself can create an actual case or controversy. *See Glaxo v. Novopharm*, 110 F.3d at 1571; *Glaxo v. Apotex*, 130 F. Supp. 2d at 1008; *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004). Apotex's submission of its ANDA demonstrates an actual and immediate controversy, concerning Apotex's significant, systematic, and deliberate actions to obtain FDA approval to sell a generic rosuvastatin calcium product.

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generic product label complete with prescribing information, warnings, and precautions. 21 C.F.R. § 314.94(a)(1)-(13).

c) The 30-Month Stay of Approval Does Not Negate Jurisdiction

Apotex proposes a *per se* rule for ANDA cases that the 30-month stay of FDA approval precludes declaratory judgment jurisdiction. However, the cases on which Apotex relies to support that proposition were governed by Federal Circuit precedent decided before the Supreme Court's *MedImmune* ruling, which rejected the Federal Circuit's prior narrow construction of declaratory judgment jurisdiction. *See, e.g., Teva*, 482 F.3d at 1334 (reversing a district court under the *MedImmune* standard, where the district court applied the reasonable apprehension of suit standard).

Apotex cites *Abbott Labs. v. Zenith Labs., Inc.,* 934 F. Supp. 925 (N.D. Ill. 1995) as ruling that a period even shorter than 30 months is not sufficiently immediate for declaratory judgment jurisdiction. In that case, unlike here, there was a significant possibility that the specification for the accused product would change, diminishing the immediacy of the controversy until the final specification of the product was known. *Id.* at 937. The patent at issue in that case covered only certain crystal forms of the active ingredient. *Id.* at 927. Because the FDA permits alternative crystal forms of an active ingredient to be used interchangeably,[4] it was possible for the defendant in *Abbott* to avoid the patent by specifying a non-infringing crystal form.

Here, however, the '314 patent claims the underlying FDA-approved active ingredient in CRESTOR®, rosuvastatin calcium. There is no possibility of designing around or otherwise

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[4] *See* FDA "Guidance for Industry: ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information", available at http://www.fda.gov/CDER/guidance/7590fnl.pdf (visited Mar. 1, 2008) ("[D]ifferences in drug substance polymorphic forms do not render drug substances different active ingredients for the purposes of ANDA approvals within the meaning of the Act and FDA regulations.") (citing 57 FR 17958, Apr. 28, 1992).

changing the active ingredient to avoid infringement. Apotex must use rosuvastatin calcium in its product. This aspect of Apotex's product will not change, and the controversy, therefore, is ripe for adjudication.

More recently, the same court that decided *Abbott* held that little more than filing an ANDA creates a sufficient controversy for declaratory judgment jurisdiction in circumstances similar to this one. *See Glaxo v. Apotex,* 130 F. Supp. 2d at 1008-09. In that case, the court exercised its declaratory judgment jurisdiction upon finding that the "defendant has filed and the FDA has accepted for filing the ANDA, which, as both parties recognize, means that the defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product." *Id.* at 1008.

Apotex selectively quoted *Abbott Diabetes Care, Inc. v. Dexcom, Inc.,* No. 05-590, 2006 WL 2375035, at *3 n.3 (D. Del. Aug. 16, 2006) to suggest that "the absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate." Apotex, however, omitted the court's preceding sentence, which states, "The court agrees with the argument [patent holder] makes in its answering brief, namely that FDA approval is not the standard by which it should evaluate whether an actual controversy existed at the time the complaint was filed." *Id.*

In fact, the absence of FDA approval in that case was not the reason for the court's declining to exercise declaratory judgment jurisdiction. Instead, the controversy was not ripe, because the final specification of the likely product was not known when the case was filed. *Id.* The FDA submission at issue was not an ANDA, but a premarket approval application for a medical device with viable non-infringing design alternatives. *Id.* at *1. Unlike generic drugs

which must use the approved active ingredient,[5] the court in *Abbott Diabetes Care* found that the "[patent holder] has not demonstrated that [defendant] produced or has prepared to produce a product that would be subject to an infringement charge under 35 U.S.C. § 271." *Id.* at *3. Significantly, the court further found that the "[patent holder] did not, and could not, allege with any certainty that 'the device when approved would be the same device that began clinical trials . . . .'" *Id.*

In contrast, the active ingredient at issue in this case, rosuvastatin calcium, must be used in Apotex's generic drug product. There is, therefore, a ripe and immediate controversy as to whether Apotex's product infringes the '314 patent.

3. Exercising Jurisdiction over Count II Will Promote Judicial Economy and Is Consistent with the Purpose and Policy of the Hatch-Waxman Act

After finding a justiciable controversy, a court has discretion to exercise declaratory judgment jurisdiction if it "would settle the legal relations in dispute and afford relief from uncertainty or insecurity . . . ." *See SanDisk*, 480 F.3d at 1383 (citing *Genentech v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993)).

a) Exercising Jurisdiction Will Not Undermine the Purpose and Policy of the Hatch-Waxman Act

Apotex mistakenly claims that AstraZeneca's "attempt to circumvent the protection against an infringement suit *prior to FDA approval* threatens to destroy" the purposes of the Hatch-Waxman Act. (D.I.. 14 at 8 (emphasis added).) There is no such protection for generic drug products. The safe harbor provided by § 271(e)(1) provides an immunity from suit for activities related to an ANDA submission to the FDA for drug approval. However, the Hatch-

[5] *See* 21 C.F.R. § 314.94(a)(5).

Waxman Act expressly contemplated that an ANDA applicant may be sued upon submitting an ANDA that certifies the applicant's intention to market the drug product before patent expiration. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990). As a result, patent infringement litigation concerning generic drug products may commence well before "premarket approval by the FDA." *See, e.g., Glaxo v. Novopharm*, 110 F.3d at 1570 (future infringement under § 271(g)); *see also Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1331-32 (Fed. Cir. 2003) (induced infringement under § 271(e)(2)); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (induced infringement under § 271(b)).

The case upon which Apotex principally relies, *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1277-78 (N.D. Cal. 1991), is distinguishable, because it involved an application to the FDA for approval of a medical device, for which the implications of the § 271(e)(1) safe harbor are quite different than for generic drug products. In that case, the patent owner asked the court to disregard the § 271(e)(1) safe harbor upon a showing that the accused infringer intended to market the medical device before patent expiration. *Id.* at 1273. The court declined to read an intent element into § 271(e)(1), noting the impracticality of ascertaining a company's intentions. *Id.* at 1274. As a result, the court ruled that "a case and controversy could arise only if either defendants [exceeded the scope of the safe harbor] or the FDA granted pre-market approval of the [medical device] and defendants began attempting to sell it in the general commercial market."[6] *Id.* at 1289.

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[6] Unlike the situation here, the court declined to exercise declaratory judgment jurisdiction because it found that "the FDA could require defendants to make changes in the [medical device] as a condition to approval. If so, the content of the dispute between these parties could change." *Intermedics*, 775 F. Supp. at 1290.

The practical effect of § 271(e)(1) is, however, different for generic drug products. The FDA statute and regulations require an ANDA applicant to certify its intentions – whether it will market the generic drug product before patent expiration or wait until the patent expires. *Eli Lilly*, 496 U.S. at 677. If the applicant certifies its intention to market the product before patent expiration, the applicant loses its immunity from patent infringement suits. *See* 35 U.S.C § 271(e)(2). Thus, Apotex wrongly asserts that § 271(e)(1) immunizes it from suit "prior to FDA approval," and the purposes and policies of the Hatch-Waxman Amendments are not undermined when ancillary claims of patent infringement under § 271(a) are brought in connection with related claims under § 271(e)(2).

Indeed, prompt resolution of all disputes regarding infringement of the '314 patent and Apotex's drug product is consistent with the purpose underlying both the declaratory judgment and Hatch-Waxman statutes. *See Teva*, 482 F.3d at 1344 ("the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes." (quoting Sen. Kennedy during debate of Medicare Modernization Act. 149 Cong. Rec. S15885 (Nov. 25, 2003))). Adjudicating AstraZeneca's declaratory judgment count for threatened infringement under § 271(a) at the same time as the infringement issues under § 271(e)(2) furthers this purpose and imposes no additional burdens on Apotex.

Finally, Apotex wrongly argues that *Abbott*, 934 F. Supp. 925 prevents this Court from exercising declaratory judgment jurisdiction over AstraZeneca's § 271(a) infringement. In *Abbott*, the court dismissed the patent owner's § 271(e)(2) count, because it had failed to properly list the underlying patent in the FDA's "Orange Book"—a prerequisite to a § 271(e)(2) action. *Id.* at 936. The court then dismissed the patent owner's claims under § 271(a) for threatened infringement explaining, "Because § 271(e)(2) cannot be invoked, the 'safe haven'

provided by § 271(e)(1) remains in force until Defendant begins to market its [generic drug product]." *Id.* at 939.

Unlike the situation in Abbott, where "§ 271(e)(2) cannot be invoked," AstraZeneca has properly invoked § 271(e)(2), and the § 271(e)(1) immunity from suit is no longer in force. Accordingly, § 271(e)(1) does not preclude the court from exercising declaratory judgment jurisdiction to efficiently and simultaneously adjudicate both the § 271(e)(2) and § 271(a) counts, and resolve all patent infringement and validity issues between AstraZeneca and Apotex in this litigation.

b) The Remedy Under Count I May Not Be Adequate

The exercise of jurisdiction under the Declaratory Judgment Act is appropriate "whether or not further relief is or could be sought." 28 U.S.C. § 2201; *Lang v. Pacific Marine and Supply Co., Ltd.*, 895 F.2d 761, 764 (Fed. Cir. 1990) ("[T]he fact that the patent owner, unlike the accused infringer, will have an express statutory remedy for infringement at a later time is irrelevant."). Nevertheless, Apotex argues that the Court should decline to exercise declaratory judgment jurisdiction because no further relief is available for infringement under 35 U.S.C. § 271(a) beyond the relief available for § 271(e)(2) infringement. AstraZeneca disagrees.

The relief requested in Count I under § 271(e)(2) focuses primarily on the subject matter of Apotex's ANDA. The relief requested in Count II under § 271(a) would prohibit all forms of infringement of the '314 patent, whether or not associated with this ANDA. It would prohibit active inducement of importation into the United States of unapproved rosuvastatin calcium from Canada or other countries where it may be marketed. It would also prohibit Apotex from entering into an agreement to market rosuvastatin calcium which is the subject of some other entity's ANDA.

It is because such declaratory judgment counts are necessary in order to fully resolve the controversy between the parties that they are regularly included in ANDA complaints and routinely litigated without incident. *See, e.g., Forest Labs., Inc. v. IVAX Pharms., Inc.*, 438 F. Supp. 2d 479 (D. Del. 2006) (Complaint included claim for patent infringement due to ANDA filing under § 271(e) and future infringing acts under § 271(a)). Apotex's motion to dismiss Count II should be denied so that the parties can proceed to completely resolve this dispute.

C. Even If this Suit Proceeds Only Against Apotex USA, the Case Should Not Be Dismissed, Because Apotex Canada Is Not an Indispensable Party

Apotex USA argues that if this Court does not have personal jurisdiction over Apotex Canada, then the entire case must be dismissed or transferred to Florida because Apotex Canada is allegedly indispensable. In support of that notion, Apotex asserts that "as the ANDA filer," Apotex Canada "is in the best position to develop evidence of patent invalidity" and Apotex Canada "would be severely prejudiced if it were unable to participate in this case." (D.I. 14 at 10.) Both assertions are logically flawed.

First, Apotex Canada's alleged status as the ANDA filer has nothing to do with patent validity. The validity of the patent will be determined primarily by patents, publications, and other information about statin drug chemistry published near or before the time rosuvastatin calcium was invented—over sixteen years ago and long before Apotex's ANDA came into existence. Evidence concerning patent validity is typically developed by the parties' lawyers from third-party sources, and both Apotex Canada and Apotex USA are represented by the same lawyers. Moreover, Apotex Canada, as the prospective manufacturer of generic rosuvastatin calcium, and Apotex USA, as the prospective marketer of it in the United States, share common economic incentives to litigate. Consequently, Apotex Canada is not any better suited to "develop evidence of patent invalidity" than Apotex USA.

Second, nothing prevents Apotex Canada from "participating in this case." Apotex Canada has evidenced its familiarity with Delaware in other significant ways, not the least of which is incorporating its subsidiary, Apotex USA, in Delaware and maintaining that Delaware incorporation. Moreover, Apotex Canada is a familiar litigant in this Court. In the past five years, Apotex Canada has participated in eight litigations in Delaware, at least one of which is still pending at very early stages.[7] Apotex Canada has had an essentially continuous and voluntary presence in the Delaware courts for purposes of conducting the ordinary business activities by which it gains access to new products. Accordingly, Apotex Canada cannot contend that it would be impossible or even inconvenient to participate here if it wished to do so. Indeed, as AstraZeneca will demonstrate in response to Apotex Canada's personal jurisdiction motion, Apotex Canada cannot even credibly deny that it is generally present in this District and subject to the Court's jurisdiction.

In further support of its argument, Apotex relies on *Frito-Lay, Inc. v. The Proctor & Gamble Co.,* 364 F. Supp. 243 (N.D. Tex. 1973), in which the patent owner was held to be an indispensible party in a patent infringement action. Apotex also relies on *Freedom, N.Y., Inc. v. United States,* No. 86-Civ. 1363-CBM, 1986 WL 6163 (S.D.N.Y., May 27, 1986), in which a government contractor was found to be an indispensible party in an action involving the

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[7] *Boehringer Ingelheim Pharmaceuticals, Inc. v. Apotex Inc. et al.*, No. 08-065 (D.Del. filed February 21, 2008 (consenting to the Court's jurisdiction). *Sanofi-Aventis and Sanofi-Aventis U.S. LLC v. Apotex Inc. and Apotex Corp.*, No. 07-792 (D. Del. filed December 6, 2007); *Senju Pharm. Co., Ltd. et al (including Allergan) v. Apotex Inc., Apotex Corp., and Apotex Pharm. India, PVT. Ltd.*, No. 07-779 (D. Del. filed November 29, 2007); *Allergan Inc. v. Apotex Inc. and Apotex Corp.*, No. 07-278 (D. Del. filed May 21, 2007); *MedPointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, No. 07-204 (D. Del. filed April 17, 2007); *Merck & Co., Inc. v. Apotex Inc.*, No. 06-230 (D. Del. filed April 7, 2006); *MedPointe Healthcare v. Apotex Inc. and Apotex Corp.*, No. 06-164 (D. Del. filed March 10, 2006); *Apotex Inc. and Apotex Corp. v. Pfizer Inc.*, No. 03-990 (D. Del. filed October 29, 2003).

government, because the economic interests of the contractor and the government were not aligned.

Here, Apotex Canada, as the alleged ANDA applicant, does not have the same status as a patent owner in a patent litigation. Moreover, even patent owners are not always indispensible parties. *Amgen, Inc. v. Ariad Pharms., Inc.,* 513 F. Supp. 2d 34 (D. Del. March 27, 2007). The factors considered in assessing the indispensability of a party are:

> [F]irst, [the extent to which] a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

Id. at 43 (emphasis added) (quoting *Gardiner v. Virgin Islands Water & Power Authority,* 145 F.3d 635, 640, (3d. Cir. 1998) (citing Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1608 at 91 (2d ed. 1986))).

Those factors support retaining Apotex USA in Delaware, even if Apotex Canada is no longer a party. First, a judgment against Apotex USA would not be unfairly prejudicial to Apotex Canada. As evidence by the two entities' retention of common counsel and their aligned economic purpose, the interests of Apotex Canada would be fairly represented in the litigation, indeed likely no differently than if Apotex Canada directly participated (unlike the government contractor and the government in the *Freedom NY* case who did not have interests in common). Second, prejudice to Apotex Canada could be further minimized by permitting its formal or informal participation in the litigation. *See Amgen,* 513 F. Supp. 2d at 43 ("If the [patent owners] believe they will be prejudiced, they can voluntarily join this action."). Finally, the judgment rendered and remedy provided if AstraZeneca prevails will be essentially the same,

even if Apotex Canada is not a party—enjoining FDA's approval of the ANDA until after patent expiration, and enjoining the commercial sale of generic rosuvastatin calcium in the United States by Apotex USA.

Indeed, adjudicating the patent infringement issues will not affect the ownership or technical merit of Apotex's ANDA. The litigation will only affect the timing of when the FDA can approve it. Moreover, the outcome of this litigation will not affect Apotex Canada's ability to manufacture or sell generic rosuvastatin calcium anywhere outside the United States. The litigation will only affect the ability to sell generic rosuvastatin calcium in the United States, a function that will be performed by Apotex USA – not Apotex Canada.

Accordingly, Apotex Canada is not an indispensible party, and this litigation can and should proceed in its absence.

V. CONCLUSION

For the forgoing reasons, the Court should deny Apotex's motion to dismiss the Complaint against it for failure to state a claim; for lack of subject matter jurisdiction; and/or for failure to join an indispensable party.

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CERTIFICATE OF SERVICE

I, hereby certify on this 27th day of March, 2008 I electronically filed the foregoing Redacted Version of DI 28, PLAINTIFFS' OPPOSITION TO APOTEX CORP.'S MOTION TO DISMISS with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

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